

1 AMY W. SCHULMAN
2 DLA PIPER LLP
3 1251 Avenue of the Americas
4 New York, NY 10020
5 Telephone: (212) 335-4500
6 Facsimile: (212) 335-4501
7 amy.schulman@dlapiper.com

5 STUART M. GORDON (SBN: 037477)
6 GORDON & REES LLP
7 Embarcadero Center West
8 275 Battery Street, Suite 2000
9 San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

10 MICHAEL C. ZELLERS (SBN: 146904)
11 TUCKER ELLIS & WEST LLP
12 515 South Flower Street, Suite 4200
13 Los Angeles, CA 90071-2223
14 Telephone: (213) 430-3400
15 Facsimile: (213) 430-3409
16 michael.zellers@tuckerellis.com

14 Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

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IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION) MDL Docket No. 1699
This document relates to)) CASE NO. 3:08-cv-1856-CRB
JACKIE LANCASTER and ROBERT RUSSELL,)) **PFIZER INC., PHARMACIA
CORPORATION, AND G.D.
SEARLE, LLC'S ANSWER TO
COMPLAINT**
Plaintiffs,))
vs.)) **JURY DEMAND ENDORSED
HEREIN**
PFIZER, INC., PHARMACIA CORPORATION,)
MONSANTO COMPANY, and G.D. SEARLE,)
LLC,)
Defendants.)

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (formerly known as "Monsanto Company"¹) ("Pharmacia"), and G.D. Searle LLC (improperly captioned in Plaintiffs' Complaint as "G.D. Searle, LLC") ("Searle") (collectively "Defendants"), and file this Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

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PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used Bextra® (valdecoxib) (“Bextra®”). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiffs were prescribed and used Bextra®.

II.

ANSWER

Response to Allegations Regarding Parties

1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance

¹ Plaintiffs' Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Bextra®. Given that Plaintiffs allege in their Complaint that Monsanto Company was involved in distributing Bextra®, *see PLAINTIFFS' COMPLAINT* at ¶ 6, Defendants assume Plaintiffs mean to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage,
5 and deny the remaining allegations in this paragraph of the Complaint.

6 2. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.
8 Defendants are without knowledge or information sufficient to form a belief as to the truth of
9 the allegations regarding whether Plaintiff used Bextra® and Plaintiff's medical condition, and,
10 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the
11 Complaint.

12 3. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.
14 Defendants are without knowledge or information sufficient to form a belief as to the truth of
15 the allegations regarding whether Plaintiff used Bextra® and Plaintiff's medical condition, and,
16 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the
17 Complaint.

18 4. Defendants admit that Pfizer is a Delaware corporation with its principal place of
19 business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
20 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
21 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
22 Bextra® in the United States, including California, to be prescribed by healthcare providers
23 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
24 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and
25 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
26 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
27 this paragraph of the Complaint.

28 5. Defendants admit that Searle is a Delaware limited liability company with its principal

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1 place of business in Illinois. Defendants admit that, during certain periods of time, Bextra®
2 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
3 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
4 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
5 deny the remaining allegations in this paragraph of the Complaint.

6 6. Defendants admit that in 1933 an entity known as Monsanto Company (“1933
7 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of
8 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name
9 to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company,
10 was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company
11 changed its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged
12 in the agricultural business and does not and has not ever manufactured, marketed, sold, or
13 distributed Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle
14 or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold,
15 or distributed Bextra®, Defendants therefore state that the 2000 Monsanto is not a proper party
16 in this matter. Defendants deny the remaining allegations in this paragraph of the Complaint.
17 Defendants state that the response to this paragraph of the Complaint regarding Monsanto is
18 incorporated by reference into Defendants’ responses to each and every paragraph of the
19 Complaint referring to Monsanto and/or Defendants.

20 7. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
21 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia
22 marketed and co-promoted Bextra® in the United States, including California, to be prescribed
23 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
24 approval by the FDA. Defendants state that Plaintiffs’ allegations regarding “predecessors in
25 interest” are vague and ambiguous. Defendants are without knowledge or information to form
26 a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the
27 remaining allegations in this Paragraph of the Complaint.

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Response to Allegations Regarding Jurisdiction and Venue

8. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

9. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are diverse and that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

10. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny committing a tort in the States of Mississippi and California, and deny the remaining allegations in this paragraph of the Complaint.

11. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants admit that they do business in the State of California. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Interdistrict Assignment

12. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. And Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

Response to Factual Allegations

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' medical condition and whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants admit that Bextra® was expected to reach consumers without substantial change from the time of sale. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations this paragraph of the Complaint.

15. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny remaining the allegations in this paragraph of the Complaint.

16. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its

1 FDA-approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendants deny the remaining allegations in this
3 paragraph of the Complaint.

4 17. The allegations in this paragraph of the Complaint are not directed toward Defendants
5 and, therefore, no response is required. To the extent a response is deemed required,
6 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this
7 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
8 form a belief as to the truth of such allegations and, therefore, deny the same.

9 18. The allegations in this paragraph of the Complaint are not directed toward Defendants
10 and, therefore, no response is required. To the extent a response is deemed required,
11 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this
12 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
13 form a belief as to the truth of such allegations and, therefore, deny the same.

14 19. The allegations in this paragraph of the Complaint are not directed toward Defendants
15 and, therefore, no response is required. To the extent a response is deemed required,
16 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this
17 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
18 form a belief as to the truth of such allegations and, therefore, deny the same.

19 20. The allegations in this paragraph of the Complaint are not directed toward Defendants
20 and, therefore, no response is required. To the extent a response is deemed required,
21 Defendants state that Plaintiffs fail to provide the proper context for the allegations in this
22 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
23 form a belief as to the truth of such allegations and, therefore, deny the same.

24 21. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the
25 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth
26 of such allegations and, therefore, deny the same.

27 22. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are
28 vague and ambiguous. Defendants are without knowledge or information to form a belief as to

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1 the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful
2 conduct and deny the remaining allegations in this paragraph of the Complaint.

3 23. Plaintiffs do not allege having used Celebrex® in this Complaint. Nevertheless,
4 Defendants admit that Celebrex® was launched in the United States in February 1999.
5 Defendants state that Celebrex® was and is safe and effective when used in accordance with its
6 FDA-approved prescribing information. Defendants admit that, during certain periods of time,
7 Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be
8 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
9 with their approval by the FDA. Defendants admit that, during certain periods of time,
10 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-
11 promoted and distributed Celebrex® in the United States to be prescribed by healthcare
12 providers who are by law authorized to prescribe drugs in accordance with their approval by the
13 FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not
14 directed toward Defendants and, therefore, no response is required. To the extent a response is
15 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the
16 allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants
17 therefore lack sufficient information or knowledge to form a belief as to the truth of such
18 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this
19 paragraph of the Complaint.

20 24. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
21 on January 15, 2001. Defendants admit, as indicated in the package insert approved by the
22 FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis
23 and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea.
24 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and
25 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
26 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
27 this paragraph of the Complaint.

28 25. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.

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1 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
2 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
3 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
4 allegations in this paragraph of the Complaint.

5 26. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
6 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
7 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
8 the remaining allegations in this paragraph of the Complaint.

9 27. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
10 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
11 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
12 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
13 prescribing information. Defendants state that the potential effects of Bextra® were and are
14 adequately described in its FDA-approved prescribing information, which at all times was
15 adequate and comported with applicable standards of care and law. Defendants deny the
16 remaining allegations in this paragraph of the Complaint.

17 28. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which at all times was adequate and comported with applicable standards of care and law.
21 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
22 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
23 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
24 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
25 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
26 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
27 with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding
28 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or

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1 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 29. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
8 this paragraph of the Complaint.

9 30. The allegations in this paragraph of the Complaint are not directed towards Defendants
10 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
11 state that the referenced article speaks for itself and respectfully refer the Court to the article for
12 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
13 the remaining allegations in this paragraph of the Complaint.

14 31. Defendants admit that the New Drug Application for Bextra® was filed with the FDA
15 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November
16 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this
17 paragraph of the Complaint.

18 32. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which at all times was adequate and comported with applicable standards of care and law.
22 Defendants deny the allegations in this paragraph of the Complaint.

23 33. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and
24 respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to
25 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this
26 paragraph of the Complaint.

27 34. Defendants state that the referenced article speaks for itself and respectfully refer the
28 Court to the article for its actual language and text. Any attempt to characterize the article is

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1 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 35. Plaintiffs fail to provide the proper context for the allegations concerning the "post-drug
3 approval meta-analysis study" in this paragraph of the Complaint. Defendants are without
4 sufficient information to confirm or deny such allegations and, therefore, deny the same.
5 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
6 the study for its actual language and text. Any attempt to characterize the study is denied.
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 36. The allegations in this paragraph of the Complaint are not directed towards Defendants
9 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
10 state that the referenced article speaks for itself and respectfully refer the Court to the article for
11 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
12 the remaining allegations in this paragraph of the Complaint.

13 37. The allegations in this paragraph of the Complaint are not directed towards Defendants
14 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
15 admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk
16 Management Advisory Committee was held on February 16-18, 2005. Defendants state that the
17 referenced testimony speaks for itself and respectfully refer the Court to the testimony for its
18 actual language and text. Any attempt to characterize the testimony is denied. Defendants
19 deny the remaining allegations in this paragraph of the Complaint.

20 38. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
22 deny the remaining allegations in this paragraph of the Complaint.

23 39. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
24 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
25 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
26 Defendants deny the remaining allegations in this paragraph of the Complaint.

27 40. Defendants state that Plaintiffs fail to provide the proper context for the allegations in
28 this paragraph of the Complaint. Defendants therefore lack sufficient information or

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1 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

2 41. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
3 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
4 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 42. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants deny the allegations in this
8 paragraph of the Complaint.

9 43. The allegations in this paragraph of the Complaint are not directed towards Defendants
10 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
11 state that the referenced article speaks for itself and respectfully refer the Court to the article for
12 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
13 the remaining allegations in this paragraph of the Complaint.

14 44. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny the allegations in this paragraph of the Complaint.

19 45. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
24 allegations in this paragraph of the Complaint.

25 46. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 47. Defendants deny the allegations in this paragraph of the Complaint.

4 48. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
5 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
6 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
7 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
8 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
9 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
10 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Bextra® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants are without knowledge or information
15 sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used
16 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
17 allegations in this paragraph of the Complaint.

18 49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
19 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
20 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
21 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
22 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
23 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
24 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Bextra® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28 applicable standards of care and law. Defendants deny the remaining allegations in this

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1 paragraph of the Complaint.

2 50. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
3 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
4 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
5 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
6 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
7 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
8 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Bextra® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants admit, as indicated in the package insert
13 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
14 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
15 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 51. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which at all times was adequate and comported with applicable standards of care and law.
20 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and
21 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
22 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
23 that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

24 52. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
25 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
26 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
27 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
28 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to

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1 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
2 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
3 effective when used in accordance with its FDA-approved prescribing information. Defendants
4 state that the potential effects of Bextra® were and are adequately described in its FDA-
5 approved prescribing information, which was at all times adequate and comported with
6 applicable standards of care and law. Defendants deny the remaining allegations in this
7 paragraph of the Complaint.

8 53. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which at all times was adequate and comported with applicable standards of care and law.
12 Defendants deny the remaining allegations in this paragraph of the Complaint.

13 54. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 55. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 56. Defendants deny the allegations in this paragraph of the Complaint.

26 57. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market
27 as of April 7, 2005. Defendants deny any wrongful conduct and deny the remaining allegations
28 contained in this paragraph of the Complaint.

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1 58. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
6 allegations in this paragraph of the Complaint.

7 59. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 60. Defendants deny any wrongful conduct and deny the remaining allegations in this
14 paragraph of the Complaint.

15 61. Defendants state that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
20 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
22 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
23 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
24 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
25 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 62. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
28 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are

1 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
2 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
3 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
4 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
5 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 63. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
9 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
11 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
12 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
13 accordance with their approval by the FDA. Defendants admit, as indicated in the package
14 insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and
15 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of
16 primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining
17 allegations in this paragraph of the Complaint.

18 64. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants are without knowledge or information sufficient to form a belief as to the truth of
23 the allegations regarding and whether Plaintiffs used Bextra® and, therefore, deny the same.
24 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
25 caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the
26 Complaint.

27 65. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants are without knowledge or information sufficient to form a belief as to the truth of
4 the allegations regarding and whether Plaintiffs used Bextra® and, therefore, deny the same.
5 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and
6 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
7 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
8 that Bextra® is defective, deny that Bextra® caused Plaintiffs injury or damage, and deny the
9 remaining allegations in this paragraph of the Complaint.

10 **Response to First Cause of Action: Negligence**

11 66. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
12 Complaint as if fully set forth herein.

13 67. Defendants state that this paragraph of the Complaint contains legal contentions to
14 which no response is deemed required. To the extent a response is deemed required,
15 Defendants admit that they had duties as are imposed by law but deny having breached such
16 duties. Defendants state that the potential effects of Bextra® were and are adequately described
17 in its FDA-approved prescribing information, which was at all times adequate and comported
18 with applicable standards of care and law. Defendants state that Bextra® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 deny the remaining allegations in this paragraph of the Complaint.

21 68. Defendants state that this paragraph of the Complaint contains legal contentions to
22 which no response is deemed required. To the extent a response is deemed required,
23 Defendants admit that they had duties as are imposed by law but deny having breached such
24 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
26 this paragraph of the Complaint.

27 69. Defendants state that this paragraph of the Complaint contains legal contentions to
28 which no response is required. To the extent that a response is deemed required, Defendants

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1 admit that they had duties as are imposed by law but deny having breached such duties.
2 Defendants state that Bextra® was and is safe and effective when used in accordance with its
3 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
4 were and are adequately described in its FDA-approved prescribing information, which was at
5 all times adequate and comported with applicable standards of care and law. Defendants deny
6 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,
7 including all subparts.

8 70. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants are without knowledge or information sufficient to form a belief as to the truth of
13 the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint.

16 71. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 72. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny
24 that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this
25 paragraph of the Complaint.

26 73. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28 74. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or

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1 damage and deny the remaining allegations in this paragraph of the Complaint.

2 75. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 **Response to Second Cause of Action: Strict Liability**

5 76. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
6 Complaint as if fully set forth herein.

7 77. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
9 same. Defendants admit that Bextra® was expected to reach consumers without substantial
10 change in the condition from the time of sale. Defendants state that Bextra® was and is safe
11 and effective when used in accordance with its FDA-approved prescribing information.
12 Defendants state that the potential effects of Bextra® were and are adequately described in its
13 FDA-approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants admit that, during certain periods of time,
15 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed
16 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
17 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
18 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
19 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
20 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
21 deny the remaining allegations in this paragraph of the Complaint.

22 78. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny the allegations in this paragraph of the Complaint.

27 79. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
4 allegations in this paragraph of the Complaint.

5 80. Defendants state that this paragraph of the Complaint contains legal contentions to
6 which no response is deemed required. To the extent a response is deemed required,
7 Defendants state that Bextra® was and is safe and effective when used in accordance with its
8 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
9 were and are adequately described in its FDA-approved prescribing information, which was at
10 all times adequate and comported with applicable standards of care and law. Defendants deny
11 that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph
12 of the Complaint, including all subparts.

13 81. Defendants state that this paragraph of the Complaint contains legal contentions to
14 which no response is deemed required. To the extent a response is deemed required,
15 Defendants state that Bextra® was and is safe and effective when used in accordance with its
16 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
17 were and are adequately described in its FDA-approved prescribing information, which was at
18 all times adequate and comported with applicable standards of care and law. Defendants deny
19 any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining
20 allegations in this paragraph of the Complaint.

21 82. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
26 caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the
27 Complaint.

28 83. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
5 allegations in this paragraph of the Complaint.

6 84. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
8 same. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
13 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
14 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
15 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
16 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
17 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
18 with their approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is
19 defective, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining
20 allegations in this paragraph of the Complaint.

21 85. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 86. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
28 same. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny the remaining allegations in this paragraph of the Complaint.

5 87. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
7 deny the remaining allegations in this paragraph of the Complaint.

8 88. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
10 same. Defendants state that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Bextra® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny that Bextra® is defective and deny the remaining allegations in this paragraph
15 of the Complaint.

16 89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 90. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 91. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 **Response to Third Cause of Action: Breach of Express Warranty**

23 92. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
24 Complaint as if fully set forth herein.

25 93. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
27 same. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants admit that they provided FDA-approved prescribing information regarding
4 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 94. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
7 same. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants admit that they provided FDA-approved prescribing information regarding
12 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint,
13 including all subparts.

14 95. Defendants deny the allegations in this paragraph of the Complaint.

15 96. Defendants state that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendants admit that they provided FDA-approved prescribing information regarding
20 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 97. Defendants state that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants admit that they provided FDA-approved prescribing information regarding
26 Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of
27 the Complaint.

28 98. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
2 same. Defendants admit that they provided FDA-approved prescribing information regarding
3 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 99. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 100. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 101. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
9 damage, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Fourth Cause of Action: Breach of Implied Warranty**

11 102. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
12 Complaint as if fully set forth herein.

13 103. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
14 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
15 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
16 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
17 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
18 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
19 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
20 paragraph of the Complaint.

21 104. Defendants admit that they provided FDA-approved prescribing information regarding
22 Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that
23 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
24 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
25 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
26 prescribing information. Defendants deny the remaining allegations in this paragraph of the
27 Complaint.

28 105. Defendants are without knowledge or information sufficient to form a belief as to the

1 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
 2 same. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
 3 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
 4 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
 5 the remaining allegations in this paragraph of the Complaint.

6 106. Defendants are without knowledge or information sufficient to form a belief as to the
 7 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
 8 same. Defendants state that Bextra® was and is safe and effective when used in accordance
 9 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
 10 this paragraph of the Complaint.

11 107. Defendants are without knowledge or information sufficient to form a belief as to the
 12 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
 13 same. Defendants state that Bextra® was expected to reach consumers without substantial
 14 change in the condition from the time of sale. Defendants deny the remaining allegations in
 15 this paragraph of the Complaint.

16 108. Defendants are without knowledge or information sufficient to form a belief as to the
 17 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
 18 same. Defendants state that Bextra® was and is safe and effective when used in accordance
 19 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
 20 deny the remaining allegations in this paragraph of the Complaint.

21 109. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
 22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 110. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
 24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 111. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
 26 damage, and deny the remaining allegations in this paragraph of the Complaint.

27 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

28 112. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'

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1 Complaint as if fully set forth herein.

2 113. Defendants state that this paragraph of the Complaint contains legal contentions to
3 which no response is deemed required. To the extent a response is deemed required,
4 Defendants admit that they had duties as are imposed by law but deny having breached such
5 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 114. Defendants state that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Bextra® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint, including all subparts.

16 115. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 116. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
27 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

28 117. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 118. Defendants deny any wrongful conduct and deny the remaining allegations in this
7 paragraph of the Complaint.

8 119. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
10 same. Defendants deny any wrongful conduct and deny the remaining allegations in this
11 paragraph of the Complaint.

12 120. Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
14 same. Defendants deny any wrongful conduct and deny the remaining allegations in this
15 paragraph of the Complaint.

16 121. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
18 same. Defendants deny any wrongful conduct and deny the remaining allegations in this
19 paragraph of the Complaint.

20 122. Defendants deny any wrongful conduct and deny the remaining allegations in this
21 paragraph of the Complaint.

22 123. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
24 same. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

1 the Complaint.

2 124. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 125. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 126. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 **Response to Sixth Cause of Action: Unjust Enrichment**

9 127. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
10 Complaint as if fully set forth herein.

11 128. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
12 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
13 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
14 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
16 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
18 paragraph of the Complaint.

19 129. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
21 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 130. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
24 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 131. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
27 same. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants deny the remaining allegations in

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1 this paragraph of the Complaint.

2 132. Defendants are without knowledge or information sufficient to form a belief as to the
 3 truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the
 4 same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
 5 damage, and deny the remaining allegations in this paragraph of the Complaint.

6 133. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or
 7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 **Response to Prayer for Relief**

9 Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief,"
 10 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage,
 11 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

12 **III.**

13 **GENERAL DENIAL**

14 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs'
 15 Complaint that have not been previously admitted, denied, or explained.

16 **IV.**

17 **AFFIRMATIVE DEFENSES**

18 Defendants reserve the right to rely upon any of the following or additional defenses to
 19 claims asserted by Plaintiffs to the extent that such defenses are supported by information
 20 developed through discovery or evidence at trial. Defendants affirmatively show that:

21 **First Defense**

22 1. The Complaint fails to state a claim upon which relief can be granted.

23 **Second Defense**

24 2. Bextra® is a prescription medical product. The federal government has preempted the
 25 field of law applicable to the labeling and warning of prescription medical products.
 26 Defendants' labeling and warning of Bextra® was at all times in compliance with applicable
 27 federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon
 28 which relief can be granted; such claims, if allowed, would conflict with applicable federal law

and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiffs and Plaintiffs' damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

21 8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or
22 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
23 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
24 liable in any way.

Ninth Defense

26 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
27 intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiffs’ treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling,

1 abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or
2 persons acting on its behalf after the product left the control of Defendants.

3 **Seventeenth Defense**

4 17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of
5 Defendants.

6 **Eighteenth Defense**

7 18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent
8 conditions unrelated to Bextra®.

9 **Nineteenth Defense**

10 19. Plaintiffs knew or should have known of any risk associated with Bextra®; therefore,
11 the doctrine of assumption of the risk bars or diminishes any recovery.

12 **Twentieth Defense**

13 20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are
14 preempted in accordance with the Supremacy Clause of the United States Constitution and by
15 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

16 **Twenty-first Defense**

17 21. Plaintiffs' claims are barred in whole or in part under the applicable state law because
18 the subject pharmaceutical product at issue was subject to and received pre-market approval by
19 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

20 **Twenty-second Defense**

21 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
22 Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes,
23 and Plaintiffs' causes of action are preempted.

24 **Twenty-third Defense**

25 23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary
26 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
27 issue under applicable federal laws, regulations, and rules.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco CA 94111

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, the Constitutions of the States of Mississippi and California, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth

1 Amendment of the United States Constitution, the Commerce Clause of the United States
 2 Constitution, and the Full Faith and Credit Clause of the United States Constitution and the
 3 Constitutions of the States of Mississippi and California. Any law, statute, or other authority
 4 purporting to permit the recovery of punitive damages in this case is unconstitutional, facially
 5 and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient
 6 standards to guide and restrain the jury's discretion in determining whether to award punitive
 7 damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate
 8 advance notice as to what conduct will result in punitive damages; (3) permits recovery of
 9 punitive damages based on out-of-state conduct, conduct that complied with applicable law, or
 10 conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits
 11 recovery of punitive damages in an amount that is not both reasonable and proportionate to the
 12 amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5)
 13 permits jury consideration of net worth or other financial information relating to Defendants;
 14 (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict
 15 review of any punitive damages awards; (7) lacks constitutionally sufficient standards for
 16 appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court
 17 precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1
 18 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North*
 19 *America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*,
 20 538 U.S. 408 (2003).

21 **Thirty-ninth Defense**

22 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
 23 and marketing of Bextra®, if any, used in this case, included adequate warnings and
 24 instructions with respect to the product's use in the package insert and other literature, and
 25 conformed to the generally recognized, reasonably available, and reliable state of the
 26 knowledge at the time the product was marketed.

27 **Fortieth Defense**

28 40. The claims asserted in the Complaint are barred because Bextra® was designed, tested,

Gordon & Rees, LLP
 275 Battery Street, Suite 2000
 San Francisco, CA 94111

1 manufactured and labeled in accordance with the state-of-the-art industry standards existing at
2 the time of the sale.

3 **Forty-first Defense**

4 41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon
5 information and belief, such injuries and losses were caused by the actions of persons not
6 having real or apparent authority to take said actions on behalf of Defendants and over whom
7 Defendants had no control and for whom Defendants may not be held accountable.

8 **Forty-second Defense**

9 42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
10 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
11 intended, and was distributed with adequate and sufficient warnings.

12 **Forty-third Defense**

13 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,
14 waiver, and/or estoppel.

15 **Forty-fourth Defense**

16 44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the
17 pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or
18 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were
19 independent of or far removed from Defendants' conduct.

20 **Forty-fifth Defense**

21 45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
22 did not proximately cause injuries or damages to Plaintiffs.

23 **Forty-sixth Defense**

24 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs
25 did not incur any ascertainable loss as a result of Defendants' conduct.

26 **Forty-seventh Defense**

27 47. The claims asserted in the Complaint are barred, in whole or in part, because the
28 manufacturing, labeling, packaging, and any advertising of the product complied with the

1 applicable codes, standards and regulations established, adopted, promulgated or approved by
2 any applicable regulatory body, including but not limited to the United States, any state, and
3 any agency thereof.

4 **Forty-eighth Defense**

5 48. The claims must be dismissed because Plaintiffs would have taken Bextra® even if the
6 product labeling contained the information that Plaintiffs contend should have been provided.

7 **Forty-ninth Defense**

8 49. The claims asserted in the Complaint are barred because the utility of Bextra®
9 outweighed its risks.

10 **Fiftieth Defense**

11 50. Plaintiffs' damages, if any, are barred or limited by the payments received from
12 collateral sources.

13 **Fifty-first Defense**

14 51. Defendants' liability, if any, can only be determined after the percentages of
15 responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if
16 any, are determined. Defendants seek an adjudication of the percentage of fault of the
17 claimants and each and every other person whose fault could have contributed to the alleged
18 injuries and damages, if any, of Plaintiffs.

19 **Fifty-second Defense**

20 52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the
21 common law gives deference to discretionary actions by the United States Food and Drug
22 Administration under the Federal Food, Drug, and Cosmetic Act.

23 **Fifty-third Defense**

24 53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is
25 comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
26 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs'
27 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
28 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,

1 and with the specific determinations by FDA specifying the language that should be used in the
 2 labeling accompanying Bextra®. Accordingly, Plaintiffs' claims are preempted by the
 3 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
 4 United States.

5 **Fifty-fourth Defense**

6 54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity
 7 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

8 **Fifty-fifth Defense**

9 55. Defendants state on information and belief that the Complaint and each purported cause
 10 of action contained therein is barred by the statutes of limitations contained in California Code
 11 of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as
 12 may apply.

13 **Fifty-sixth Defense**

14 56. Defendants state on information and belief that any injuries, losses, or damages suffered
 15 by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable
 16 conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against
 17 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

18 **Fifty-seventh Defense**

19 57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of
 20 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
 21 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
 22 damages is also barred under California Civil Code § 3294(b).

23 **Fifty-eighth Defense**

24 58. To the extent that Plaintiffs rely upon any theory of breach of warranty, Plaintiffs'
 25 claims are barred because Defendants did not make or breach any express or implied
 26 warranties, Plaintiffs failed to give reasonable notice to Defendants of any alleged breach or
 27 breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

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 275 Battery Street, Suite 2000
 San Francisco, CA 94111

[Fifty-ninth Defense](#)

59. Any verdict or judgment rendered against Defendant must be reduced under the laws of the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiffs, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiffs may have settled their claims for alleged injuries and damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiffs and any such parties.

Sixtieth Defense

60. Plaintiffs' claims for punitive damages are limited or barred by the standards governing exemplary damage awards which arise under the United States Constitution and decisions of the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi Constitution, statutes, and decisions of Mississippi courts.

Sixty-first Defense

61. Defendant asserts that Plaintiffs' claim for punitive damages is governed and limited by Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the same.

Sixty-second Defense

62. Bextra® and the Defendants' actions conformed to the state of the art medical and scientific knowledge at all times relevant to this lawsuit and Bextra® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

Sixty-third Defense

63. Defendants satisfied their duty to warn under the learned intermediary doctrine and Plaintiffs' claims are therefore barred.

Sixty-fourth Defense

64. Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and

1 hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

2 **Sixty-fifth Defense**

3 65. Plaintiffs failed to join all indispensable parties; as a result of such failure to join,
 4 complete relief cannot be accorded to those already parties to the action and will result in
 5 prejudice to Defendant in any possible future litigation.

6 **Sixty-sixth Defense**

7 66. Any judicially-created definitions of manufacturing defect and design defect, and
 8 standards for determining whether there has been an actionable failure to ward, are
 9 unconstitutional in that, among other things, they are void for vagueness and undue burden on
 10 interstate commerce, as well as an impermissible effort to regulate in an area that previously has
 11 been preempted by the federal government.

12 **Sixty-seventh Defense**

13 67. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of
 14 Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any
 15 award of punitive damages is barred.

16 **Sixty-eighth Defense**

17 68. Plaintiffs' claims are barred in whole or in part because Plaintiffs lack standing to bring
 18 such claims.

19 **Sixty-ninth Defense**

20 69. Defendants reserve the right to supplement their assertion of defenses as they continue
 21 with their factual investigation of Plaintiffs' claims.

22 **V.**

23 **PRAYER**

24 WHEREFORE, Defendants pray for judgment as follows:

25 1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
 26 2. That the Complaint be dismissed;
 27 3. That Defendants be awarded their costs for this lawsuit;
 28 4. That the trier of fact determine what percentage of the combined fault or other liability

1 of all persons whose fault or other liability proximately caused Plaintiffs' alleged
2 injuries, losses or damages is attributable to each person;

3 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater
4 than an amount which equals their proportionate share, if any, of the total fault or other
5 liability which proximately caused Plaintiffs' injuries and damages; and
6 6. That Defendants have such other and further relief as the Court deems appropriate.

7 May 15, 2008

8 GORDON & REES LLP

9
10 By: _____/s/
11 Stuart M. Gordon
12 sgordon@gordonrees.com
13 Embarcadero Center West
14 275 Battery Street, 20th Floor
15 San Francisco, CA 94111
16 Telephone: (415) 986-5900
17 Fax: (415) 986-8054

18 May 15, 2008

19 TUCKER ELLIS & WEST LLP

20
21 By: _____/s/
22 Michael C. Zellers
23 michael.zellers@tuckerellis.com
24 515 South Flower Street, Suite 4200
25 Los Angeles, CA 90071-2223
26 Telephone: (213) 430-3400
27 Fax: (213) 430-3409

28
29 Attorneys for Defendants
30 PFIZER INC., PHARMACIA
31 CORPORATION, AND G.D. SEARLE
32 LLC

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

1 **JURY DEMAND**

2 Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a
3 trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil
4 Procedure.

5 May 15, 2008

GORDON & REES LLP

6

7 By: _____ /s/
8 Stuart M. Gordon
9 sgordon@gordonrees.com
10 Embarcadero Center West
11 275 Battery Street, 20th Floor
12 San Francisco, CA 94111
13 Telephone: (415) 986-5900
14 Fax: (415) 986-8054

15 May 15, 2008

TUCKER ELLIS & WEST LLP

16 By: _____ /s/
17 Michael C. Zellers
18 michael.zellers@tuckerellis.com
19 515 South Flower Street, Suite 4200
20 Los Angeles, CA 90071-2223
21 Telephone: (213) 430-3400
22 Fax: (213) 430-3409

23 Attorneys for Defendants
24 PFIZER INC., PHARMACIA
25 CORPORATION, AND G.D. SEARLE
26 LLC

27 **Gordon & Rees, LLP**
28 **275 Battery Street, Suite 2000**
29 **San Francisco, CA 94111**